

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STANLEY KOSHY,

Plaintiff,

V.

REGENERON PHARMACEUTICALS, INC.,

Defendant.

OPINION AND ORDER

17 CV 7781 (VB)

Briccetti, J.:

Plaintiff, proceeding pro se, brings claims against defendant Regeneron Pharmaceuticals, Inc. (“Regeneron”), for violation of the anti-retaliation provision of the False Claims Act (the “FCA”), 31 U.S.C. § 3730(h), and for violation of the New York Labor Law (“NYLL”) § 740.

Now pending is Regeneron's motion for summary judgment. (Doc. #58).

For the following reasons, the motion is GRANTED.

The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1367.

BACKGROUND

The parties have submitted briefs, statements of material facts, supporting declarations, and exhibits, which reflect the following factual background.¹

Throughout plaintiff's opposition, plaintiff asserts Regeneron failed to produce documents in response to his discovery requests. Plaintiff does not provide any basis for finding Regeneron violated any discovery obligation. Further, although plaintiff is currently proceeding pro se, he was represented by retained counsel at the beginning of discovery and by limited discovery pro bono counsel after his retained counsel withdrew. Moreover, there were no unresolved discovery issues when discovery closed. In the brief period during which plaintiff proceeded pro se, he once applied for discovery relief. (Doc. #38). However, plaintiff's limited pro bono counsel subsequently resolved that application with defense counsel (Doc. #46), and plaintiff did not make any additional requests for discovery relief. Accordingly, to the extent plaintiff now seeks discovery relief, he is not entitled to any.

I. Plaintiff's Position at Regeneron

Regeneron is a biopharmaceutical company that develops, manufactures, and commercializes medicine for the treatment of serious medical conditions. Plaintiff worked for Regeneron as manager of contract manufacturing organization (“CMO”) strategic relationships from May 2, 2016, until he was terminated on October 11, 2016. In that position, plaintiff acted as the primary liaison between Regeneron and its CMOs.

Plaintiff was responsible for coordinating all manufacturing activities at the CMO sites, scheduling batches, supplying requested materials, directing shipments of bulk and finished product, tracking outputs and project step completion times, and providing associated reports. Plaintiff's job duties also included “uphold[ing] product integrity and company reputation by assisting in the monitoring of cGMP [Current Good Manufacturing Practices] compliance at contract manufacturers”; “support[ing] internal investigations or deviation reports which concern contract manufacturing or associated shipping operations”; and “help[ing] drive appropriate corrective or preventive actions.” (Doc. #61 (“Fitzpatrick Decl.”) Ex. 5 at REG0000173).² Finally, plaintiff was responsible for “provid[ing] regulatory filing support when needed.” (*Id.*).

II. Alleged Complaints to Regeneron

Plaintiff alleges he discovered “numerous issues regarding CMO sites” and brought them to the attention of his supervisor and project managers at Regeneron. (Doc. #3 (“Compl.”) ¶ 16).

² “Doc. #__ at __” refers to the Bates-stamped numbers in the bottom-right corner of the parties’ exhibits. “Doc. #__ at ECF __” refers to the page numbers automatically assigned by the Court’s Electronic Case Filing system. In addition, “Pl. Dep.” refers to Doc. #66 at ECF 69–357; “Pl. Dep. at __” refers to the page numbers in the top-right of the transcript of plaintiff’s deposition.

A. Pre-Filtration Bioburden Testing

First, plaintiff alleges he expressed concerns that Regeneron would implement revised pre-filtration bioburden (viable bacteria or fungus cell) testing levels in their drug manufacturing process without requisite change controls.³

In June 2016, Regeneron implemented a new European guideline that provided that drug manufacturers should utilize pre-filtration bioburden sample volumes of ten colony-forming units (CFU) per 100 milliliters (mL) instead of one CFU per 10 mL, a more sensitive testing process than previously used.

Plaintiff attended a meeting on June 4, 2016, regarding the new procedure. Plaintiff was assigned to set up meetings every two to three weeks to monitor the progress of implementing the new pre-filtration bioburden requirement. The meeting minutes also provided there would be “regulatory impact” attendant to the new procedures. (Fitzpatrick Decl. Ex. 11 at REGE0000406).

The next day plaintiff emailed several employees asking whether there would be “any potential impact associated with regulatory filings.” (Fitzpatrick Decl. Ex. 12 at REGE0000215). Another employee responded in the affirmative. Plaintiff then asked, “Is QA & Legal authorizing the memo.” (*Id.*). The employee responded saying he did not think they needed to involve legal because the request to implement the new procedure was “from regulatory.” (*Id.*). The employee also stated a change control was pending.

³ According to Regeneron’s manager of product quality, a “change control” refers to the process a company uses to manage changes that it makes to internal processes, primarily through the assigned responsibilities of the quality control unit. (Fitzpatrick Decl. Ex. 10 (“Molloy Decl.”) ¶ 5). Thus, change control activities “include quality planning and control of revisions to specifications, process parameters, and procedures.” (*Id.*). According to the same employee (and undisputed by plaintiff), the Food and Drug Administration (“FDA”) does not require companies to file their change control documentation.

Plaintiff forwarded this correspondence to his supervisor, James Jackson, and wrote, “FYI.” (Fitzpatrick Decl. Ex. 12 at REGE0000215). Plaintiff testified at his deposition he believed Jackson thought it was a minor issue. Plaintiff further testified he did not believe his email to Jackson constituted a complaint, but that he also had verbally suggested to Jackson that Regeneron follow the change control. He testified he did not tell Jackson that he thought Regeneron was “violating the law,” “doing something wrong,” “defrauding the government,” or “putting the health and safety of patients and the public in jeopardy,” concerning the “bioburden issue.” (Pl. Dep. at 202).

B. Drug Substance “Lots” at Cook Pharmica CMO

Second, on June 30, 2016, plaintiff learned Cook Pharmica, one of Regeneron’s CMOs, had used two “lots” of a drug substance to fill a “batch,” rather than one lot. (Fitzpatrick Decl. Ex. 17 at REGE0000289).⁴ Regeneron had originally instructed Cook Pharmica to use two lots per batch, but Regeneron then revised that instruction to use only one lot per batch—an instruction that Cook Pharmica apparently had missed. After plaintiff learned that Cook Pharmica had used two lots in a batch, a meeting was scheduled at Regeneron for later that day to discuss the status of the batch and to review Cook Pharmica and Regeneron procedures to ensure the problem did not recur.

Plaintiff attended the June 30, 2016, meeting. Meeting minutes state: “Discussion outcome was there is no impact to Quality of the manufactured batch or availability for Clinical

⁴ “Lot means a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits.” 21 C.F.R. § 210.3(b)(10). “Batch means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.” *Id.* § 210.3(b)(2).

Use. . . . At the Regeneron / Cook Team Meeting both Quality Management Departments agreed no deviation was required.” (Fitzpatrick Decl. Ex. 18 at P00195). The minutes also state, “Cook Acknowledged seriousness of not following revised allocation and possible impact to the batch. Cook is reviewing process of document control and use with Cook SharePoint and has committed to improving the system to minimize the potential of this type of event occurring.” (Id.). The minutes further suggest an “enhancement to the SharePoint system” and state, “Regeneron team to work closely with the Cook Project Management team to ensure collaboration between companies to successfully manufacture batches.” (Id.).

Plaintiff testified at his deposition that he did not agree with the decision that no deviation was required, but plaintiff stayed silent because it was “quality’s call.” (Pl. Dep. at 213).

C. Supply Chain Gap Analysis

Third, plaintiff was invited to a meeting to discuss performing a “gap analysis” of Regeneron’s supply chain, as Regeneron had identified suppliers and CMO sites not on Regeneron’s approved supplier list. (Fitzpatrick Decl. Ex. 19 at P00012). Plaintiff replied to the meeting invitation with the title of and a hyperlink to an article regarding financial considerations in CMO selection and management. Plaintiff then forwarded his email with the article to Jackson. Plaintiff testified he could not remember whether he sent additional emails regarding the supply chain gap analysis.

Relatedly, plaintiff also testified he suggested at a meeting that Regeneron create and maintain a spreadsheet to track certificates of compliance. According to plaintiff, his approach was adopted and a spreadsheet was created. Plaintiff did not reach out to the attendees of that meeting to say they were not doing enough to address his concerns. Plaintiff testified he “was

happy that at least the team is going in the right direction and I didn't want to disgrace the team.” (Pl. Dep. at 186). He also agreed that they “were handling it appropriately,” although “they should have done [that] two or three years back.” (Id.).

D. Shipment of Rejected Product

Fourth, on July 16, 2016, plaintiff emailed his colleague John Fredericks for details regarding a shipment to “packaging” of a rejected lot for engineering study purposes. (Fitzpatrick Decl. Ex. 22 at REGE0000785). Fredericks responded the rejected lot was needed for “pack and label,” and that the lot was rejected “due to bioburden hit.” (Id.). Plaintiff and Fredericks exchanged several more emails in which plaintiff expressed concern about shipping the rejected lot and stated they needed to “check with compliance.” (Id. at REGE0000784). Fredericks explained that the material was needed to “test machine,” and that he had already checked with compliance. (Id.). Plaintiff then forwarded their correspondence to Jackson and wrote above it, “FYI.” (Id. at REGE0000778).

Plaintiff and Fredericks exchanged more emails. Ultimately, fewer than fifteen minutes after plaintiff first forwarded their correspondence to Jackson, plaintiff forwarded the additional correspondence to Jackson and to an employee in quality assurance and wrote, “FYI, Please the response below. No action needed.” (Fitzpatrick Decl. Ex. 22 at REGE0000782).

E. Zika Virus Preclinical Program

Fifth, plaintiff was involved with initial work on a project related to the Zika virus. However, Jackson subsequently chose another employee to lead the Zika project team. Plaintiff emailed Jackson to complain about the decision to choose someone else.

In an interrogatory response, plaintiff stated he expressed concerns to Jackson about change controls regarding the Zika virus project, and “was concerned that without them false

information regarding the results would be sent to the FDA in reliance of continued government funding.” (Fitzpatrick Decl. Ex. 32 at ECF 9).

F. General Compliance Concerns

Finally, plaintiff sent Regeneron’s CEO an email on August 1, 2016, complaining because he had been suspended without pay. Plaintiff asserted the suspension was in retaliation for raising concerns of a “hostile work environment.” (Fitzpatrick Decl. Ex. 28 at P00288). Plaintiff sent a follow-up email on August 5, 2016, stating he was not satisfied with a subsequent discussion with human resources and his boss. Plaintiff also wrote: “Emails documented including major compliance issues.” (Fitzpatrick Decl. Ex. 29 at P00219). Plaintiff did not elaborate further.

DISCUSSION

I. Standard of Review

The Court must grant a motion for summary judgment if the pleadings, discovery materials before the Court, and any affidavits show there is no genuine issue as to any material fact and it is clear the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).⁵

A fact is material when it “might affect the outcome of the suit under the governing law Factual disputes that are irrelevant or unnecessary” are not material and thus cannot preclude summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

A dispute about a material fact is genuine if there is sufficient evidence upon which a reasonable jury could return a verdict for the non-moving party. See Anderson v. Liberty Lobby,

⁵ Unless otherwise indicated, case quotations omit all internal citations, quotations, footnotes, and alterations.

Inc., 477 U.S. at 248. The Court “is not to resolve disputed issues of fact but to assess whether there are any factual issues to be tried.” Wilson v. Nw. Mut. Ins. Co., 625 F.3d 54, 60 (2d Cir. 2010) (citation omitted). It is the moving party’s burden to establish the absence of any genuine issue of material fact. Zalaski v. City of Bridgeport Police Dep’t, 613 F.3d 336, 340 (2d Cir. 2010).

If the non-moving party has failed to make a sufficient showing on an essential element of his case on which he has the burden of proof, then summary judgment is appropriate. Celotex Corp. v. Catrett, 477 U.S. at 323. If the non-moving party submits “merely colorable” evidence, summary judgment may be granted. Anderson v. Liberty Lobby, Inc., 477 U.S. at 249–50. The non-moving party “must do more than simply show that there is some metaphysical doubt as to the material facts, and may not rely on conclusory allegations or unsubstantiated speculation.” Brown v. Eli Lilly & Co., 654 F.3d 347, 358 (2d Cir. 2011). The mere existence of a scintilla of evidence in support of the non-moving party’s position is likewise insufficient; there must be evidence on which the jury could reasonably find for him. Dawson v. County of Westchester, 373 F.3d 265, 272 (2d Cir. 2004).

On summary judgment, the Court construes the facts, resolves all ambiguities, and draws all permissible factual inferences in favor of the non-moving party. Dallas Aerospace, Inc. v. CIS Air Corp., 352 F.3d 775, 780 (2d Cir. 2003). If there is any evidence from which a reasonable inference could be drawn in favor of the non-moving party on the issue on which summary judgment is sought, summary judgment is improper. See Sec. Ins. Co. of Hartford v. Old Dominion Freight Line, Inc., 391 F.3d 77, 82–83 (2d Cir. 2004).

In deciding a motion for summary judgment, the Court need only consider evidence that would be admissible at trial. Nora Beverages, Inc. v. Perrier Grp. of Am., Inc., 164 F.3d 736, 746 (2d Cir. 1998).

II. FCA Retaliation Claim

Regeneron argues plaintiff's FCA retaliation claim fails as a matter of law because plaintiff did not engage in protected activity under the FCA and because Regeneron was not aware plaintiff was engaged in protected activity.

The Court agrees.

The FCA is an anti-fraud statute that “imposes liability on any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval or who knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.” United States ex rel. Chorchos for Bankr. Estate of Fabula v. Am. Med. Response, Inc., 865 F.3d 71, 81 (2d Cir. 2017). “The FCA defines a ‘claim’ as any request or demand for money or property that is presented, directly or indirectly, to the United States.” Id. “A claim is false within the meaning of the FCA if it falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.” United States ex rel. Ladas v. Exelis, Inc., 824 F.3d 16, 26 (2d Cir. 2016) (emphasis removed). “Not every breach of a federal contract gives rise to FCA liability, . . . but a defendant is liable when it submits a claim for reimbursement while knowing that payment expressly is precluded because of some noncompliance by the defendant.” Id.

The FCA's anti-retaliation provision provides:

[a]ny employee . . . shall be entitled to all relief necessary to make that employee . . . whole, if that employee . . . is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee . . . in furtherance of

an action under this section or other efforts to stop 1 or more violations of [the FCA].

31 U.S.C. § 3730(h)(1). “[T]he Second Circuit has yet to articulate a test for deciding when a plaintiff has set forth a claim for retaliation under section 3730(h).” Ortiz v. Todres & Co., 2019 WL 1207856, at *4 (S.D.N.Y. Mar. 14, 2019).⁶ However, “courts generally require a plaintiff to show that (1) he engaged in activity protected under the statute, (2) the employer was aware of such activity, and (3) the employer took adverse action against him because he engaged in the protected activity.” Dhaliwal v. Salix Pharm., Ltd., 752 F. App’x 99, 100 (2d Cir. 2019) (summary order).

A. Protected Activity

There is no evidence plaintiff engaged in protected activity under the FCA.

“Protected activity” is “interpreted broadly, . . . and encompasses two kinds of conduct: (1) lawful acts done by the employee . . . in furtherance of an action under the FCA, and (2) other efforts to stop one or more violations of the FCA.” Swanson v. Battery Park City Auth., 2016 WL 3198309, at *3 (S.D.N.Y. June 8, 2016). Some courts have also held that determining whether an employee’s conduct constitutes protected activity involves a subjective and objective test. Ortiz v. Todres & Co., 2019 WL 1207856, at *4. In those cases, courts evaluate “whether (1) the employee in good faith believes, and (2) a reasonable employee in the same or similar circumstances might believe, that the employer is committing fraud against the government.” Id.

“It is enough to show that a plaintiff’s investigation reasonably could have led to an FCA action.” Dhaliwal v. Salix Pharm., Ltd., 752 F. App’x at 100. However, “even under the broadest reading of . . . ‘in furtherance of an [FCA] action,’ an employee’s activities that are not

⁶ Plaintiff will be provided with copies of all unpublished opinions cited in this decision. See Lebron v. Sanders, 557 F.3d 76, 79 (2d Cir. 2009).

related to exposing or deterring fraud, are not whistle blowing as envisioned in the paradigm qui tam FCA action.” Ortiz v. Todres & Co., 2019 WL 1207856, at *4. “Although correcting regulatory problems may be a laudable goal, those problems are not actionable under the FCA in the absence of actual fraudulent conduct, and so reporting them falls outside the purview of the FCA’s anti-retaliation provision.” Lawrence v. Int’l Bus. Mach. Corp., 2017 WL 3278917, at *6 (S.D.N.Y. Aug. 1, 2017). “In other words, merely grumbling to the employer about job dissatisfaction or regulatory violations does not constitute protected activity.” Id.

Here, the undisputed evidence demonstrates plaintiff did not engage in protected activity. Plaintiff fails to satisfy the objective test because no reasonable employee in the same or similar circumstances would have believed, based on the undisputed evidence presented in this case, that Regeneron committed fraud against the government. Plaintiff did not submit any evidence that Regeneron was engaged in fraud, and none of plaintiff’s complaints at Regeneron involved exposing or deterring fraud. At most, plaintiff was concerned Regeneron would violate FDA regulations because of its allegedly deficient quality control mechanisms, which is insufficient to sustain an FCA retaliation claim.

Plaintiff also fails to satisfy the subjective test. Plaintiff has not submitted any evidence he believed Regeneron presented to the United States any false claims, claims with material omissions, or claims that failed to comply with statutory, regulatory, or contractual requirements; that such requirements were a prerequisite to payment; or that Regeneron received money to which it was not entitled. Cf. Lawrence v. Int’l Bus. Mach. Corp., 2017 WL 3278917, at *8 (dismissing FCA retaliation claim for failure to allege protected activity). Indeed, in response to an interrogatory, plaintiff admitted he “cannot identify any false claims submitted to the government for reimbursement as a result of the practices alleged in the complaint.” (Fitzpatrick

Decl. Ex. 32 at ECF 12). Plaintiff also admitted in response to an interrogatory that he could not describe how Regeneron caused the submission of any false claim. (Id. at 12–13).

The record further demonstrates that even if plaintiff's concerns were related to the submission of false or fraudulent claims, plaintiff did not actually raise those concerns to anyone at Regeneron. First, regarding pre-filtration bioburden testing, plaintiff testified he did not tell Jackson that he thought Regeneron was “violating the law,” “doing something wrong,” “defrauding the government,” or “putting the health and safety of patients and the public in jeopardy,” as concerning “the bioburden issue.” (Pl. Dep. at 202).

Second, concerning Cook Pharmica CMO's mistakenly using two lots to fill a batch instead of one, plaintiff testified that although he did not agree with his Regeneron colleagues' decision that no deviation was required, he stayed silent because it was “quality's call.” (Pl. Dep. at 213).

Third, regarding the supply chain gap analysis, plaintiff has not submitted any evidence of anything that could be construed as a complaint. The only evidence in the record shows plaintiff replied to a meeting invitation regarding initiating a supply chain gap analysis with an article about the financial considerations in CMO selection and management. As for the related matter of tracking certificates of compliance, plaintiff testified he did not raise concerns because he “didn't want to disgrace the team,” and thought his team was appropriately handling the issue. (Pl. Dep. at 186).

Fourth, concerning the shipment to packaging of a rejected lot for engineering study purposes, plaintiff merely forwarded correspondence to his supervisor with an “FYI” in the body of the message. (Fitzpatrick Decl. Ex. 22 at REGE0000782). Then, less than fifteen minutes later, plaintiff told his supervisor no action was needed.

Fifth, the only evidence regarding the Zika virus project is plaintiff's email to Jackson complaining he was not chosen to be on the Zika virus project team—plaintiff has not submitted any evidence to support his assertion that he expressed concerns to Jackson about change controls regarding the Zika virus project.

Finally, plaintiff's email to Regeneron's CEO concerning compliance issues did not actually state with what plaintiff took issue. All plaintiff wrote was: "Emails documented including major compliance issues." (Fitzpatrick Decl. Ex. 29 at P00219).

Plaintiff argues Regeneron's certification that one hundred percent of its units meet the bioburden and sterility tests is false because Regeneron has deficient quality management systems. But that allegation is conclusory. Plaintiff has not identified any document in which Regeneron certified that one hundred percent of its units meet the bioburden and sterility tests. Plaintiff has also not presented any evidence that such a certification would be false—i.e., any evidence Regeneron's units did not meet bioburden and sterility tests. Plaintiff has merely suggested that deficient quality control could have led to failing those tests. Plaintiff's assertion thus amounts to pure speculation.

A similar problem lies in plaintiff's reliance on two audit reports of Cook Pharmica: one by the FDA from April and May 2018 (Koshy Decl. at ECF 375), and one by Regeneron from October 2016 (Koshy Decl. at ECF 447). Neither of those documents suggests Regeneron made any false statement in any report to the government. In fact, to the contrary, the FDA audit suggests the government was aware of some of the quality control problems at Cook Pharmica with which plaintiff was concerned.

Plaintiff also asserts his complaints were proven valid when, from May 2017 to February 2018, 143 cases of inflammation associated with Regeneron's EYLEA aflibercept (an eye

medication) were reported to the American Society of Retina Specialists. Plaintiff further asserts Regeneron was reimbursed for claims it submitted to the government involving EYLEA. But there is no evidence plaintiff complained about the manufacture or production of EYLEA while he was at Regeneron—indeed, the increase in reports of inflammation seemingly occurred after plaintiff’s employment; plaintiff has not submitted any evidence (besides his own unsworn say-so) suggesting poor quality controls caused the increase in inflammation cases; and plaintiff has not identified any document in which Regeneron made a false statement about ELYEA.

Accordingly, Regeneron is entitled to summary judgment on plaintiff’s FCA retaliation claim because there is no evidence plaintiff engaged in protected activity under the FCA.

B. Notice

Even if plaintiff had engaged in protected activity under the FCA, Regeneron was not on notice that plaintiff was engaging in protected activity.

A plaintiff must do more than raise “generalized concerns” to put its employer on notice. Dhaliwal v. Salix Pharm., Ltd., 752 F. App’x 99 at 101. Moreover, “[p]laintiffs alleging that performance of their normal job responsibilities constitutes protected activity must overcome the presumption that they are merely acting in accordance with their employment obligations.” Ortiz v. Todres & Co., 2019 WL 1207856, at *5. “An employee who simply engages in behavior wholly consistent with his job description will not, without more, provide notice that he is engaging in a protected activity.” Id.

Plaintiff testified at his deposition he never told anyone at Regeneron that: (i) he believed the government had been billed for product that was actually adulterated; (ii) the government had been billed in a fraudulent manner; or (iii) Regeneron had defrauded the

government. (Pl. Dep. at 171). That alone demonstrates Regeneron was not on notice that plaintiff was engaging in protected activity.

In addition, plaintiff's complaints, to the extent he made any, fell within his job description. Plaintiff's concerns involving (i) the potential regulatory impact of new pre-filtration bioburden testing; (ii) Cook Pharmica's mistaken use of two lots, rather than one, to fill a batch; (iii) the supply chain gap analysis; and (iv) proper change controls in the Zika virus preclinical program, all fall under plaintiff's job duty to "uphold[] product integrity and company reputation by assisting in the monitoring of cGMP compliance at contract manufacturers." (Fitzpatrick Decl. Ex. 5 at REG0000173). And plaintiff's concern regarding a shipment to packaging of a rejected lot for engineering study purposes falls under his job duty to "support[] internal investigations or deviation reports concerning contract manufacturing or associated shipping operations." (*Id.*). Therefore, plaintiff was required to overcome the presumption that he was acting in accordance with his job duties. Plaintiff has not presented any evidence to overcome that presumption.

Accordingly, Regeneron is entitled to summary judgment in its favor on plaintiff's FCA retaliation claim for the independent and additional reason that it was not on notice that plaintiff was engaging in protected activity under the FCA.

III. NYLL Claim

Regeneron also argues plaintiff's NYLL claim fails as a matter of law because plaintiff has not articulated a law, rule, or regulation that Regeneron violated.

The Court agrees.

Section 740 prohibits an employer from taking any retaliatory personnel action against an employee "because such employee . . . discloses, or threatens to disclose to a supervisor or to a

public body an activity, policy or practice of the employer that is in violation of law, rule or regulation which violation creates and presents a substantial and specific danger to the public health or safety.” N.Y. Labor Law § 740(2)(a). Thus, “[t]o prevail under Section 740, a plaintiff who has suffered an adverse employment action must establish that: (1) he disclosed or threatened to disclose an activity, policy, or practice of his employer to a supervisor or public body, (2) the underlying activity, policy, or practice constituted an actual violation of a law, rule, or regulation, . . . (3) the violation presented a substantial and specific danger to the public,” and (4) “the adverse employment action was taken ‘because’ of his disclosure or threatened disclosure of the violation.” Rivera v. Affineco LLC, 2018 WL 2084152, at *3 (S.D.N.Y. Mar. 26, 2018).

With respect to the second element, “[t]he violation of a law, rule or regulation necessary to trigger the protections afforded by Section 740 is not limited to criminal violations, but also includes violations of civil and administrative statutes, rules and regulations.” DeCarlo v. Mass. Elec. Constr. Co., 1995 WL 122720, at *7 (S.D.N.Y. Mar. 22, 1995). However, “a mere good-faith reasonable belief that an actual violation occurred is insufficient to impose liability.” Rivera v. Affineco LLC, 2018 WL 2084152, at *3. Thus, a plaintiff is required to “specify the law, rule or regulation that has actually been violated by defendants’ behavior.” Hakim v. Hall, 2009 WL 5910310, at *11 (S.D.N.Y. Oct. 23, 2009), report and recommendation adopted in part sub nom. DD v. Lincoln Hall, 2010 WL 695027 (S.D.N.Y. Feb. 19, 2010). A plaintiff’s conclusory assertion that a defendant violated the law, without more, is insufficient to support a claim under Section 740. See Frank v. Walgreens Co., 2011 WL 4465210, at *5 (E.D.N.Y. Sept. 26, 2011) (collecting cases).

Plaintiff fails to satisfy the second element because he does not identify the specific laws, rules, or regulations that defendants violated. In plaintiff's opposition and response to Regeneron's statement of undisputed material facts, plaintiff lists several FDA and European Union regulations, which he divides into three categories: "Good Laboratory Practice," "Good Clinical Practice," and "Good Manufacturing Practice." (Doc. #65 at ECF 13). Within those categories, plaintiff broadly cites to whole Parts of the Code of Federal Regulations (CFR), but does not indicate which specific provisions of the CFR Regeneron violated or how Regeneron violated them. At most, plaintiff's allegations amount to a conclusory assertion that Regeneron broadly had deficient quality management system practices.

Plaintiff also appears to rely on 21 C.F.R. §§ 211.100 and 211.160. Those regulations mandate written change controls and contain general requirements for laboratory controls, respectively. Plaintiff has not presented any evidence suggesting how Regeneron violated those provisions or explained how any such violation presented a substantial and specific danger to the public.

In addition, plaintiff testified at his deposition that he believed Regeneron violated 21 C.F.R. § 211.65, which requires that equipment and substances not contact materials that would improperly alter a medicinal product. But plaintiff cannot identify any instance in which such contamination occurred—i.e., an instance in which Regeneron violated that regulation. To the contrary, plaintiff testified the manufacturing and compliance issues with which he was concerned did not result in adulterated products.

Accordingly, Regeneron is entitled to judgment as a matter of law in its favor on plaintiff's NYLL claim.

CONCLUSION

The motion for summary judgment is GRANTED.

The Clerk is instructed to terminate the motion (Doc. #58) and close this case.

The Court certifies pursuant to 28 U.S.C. § 1915(a)(3) that any appeal from this order would not be taken in good faith, and therefore in forma pauperis status is denied for the purpose of an appeal. See Coppedge v. United States, 369 U.S. 438, 444–45 (1962).

Dated: December 16, 2019
White Plains, NY

SO ORDERED:

A handwritten signature in black ink, appearing to read 'Vincent Briccetti', written over a horizontal line.

Vincent L. Briccetti
United States District Judge